

LUMMI INDIAN BUSINESS COUNCIL

2616 KWINA ROAD • BELLINGHAM, WASHINGTON 98226-9298 • (360) 384-1489

DEPARTMENT _____

EXT. _____

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

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April 20, 1999

Dear Sirs:

This letter is in response to Docket No. 98P-0504, a petition from the Center for Science in the Public Interest (CSPI), dated June 21, 1998. This petition requests regulatory action to establish a regulation requiring non-detectable levels of *Vibrio vulnificus* in raw molluscan shellfish harvested from waters that have been linked to illnesses or deaths from *V. vulnificus*.

The Lummi Nation is a successor to several tribes that signed the Treaty of Point Elliott in 1855 which reserved the right to harvest fish and shellfish at usual and accustomed fishing grounds and stations. The Lummi Nation commercially harvests some 630,000 pounds per year of clams and oysters from on-reservation culture and natural production, and off reservation natural production in Washington State pursuant to orders of the federal court. The proposed action could cause significant harm to those who depend upon commercial shellfish harvests to sustain them by increasing production costs without significant increased benefits to the consumers.

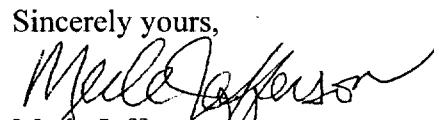
The Lummi Nation requests that the FDA delay consideration of specific regulations establishing performance standards for the following reasons:

1. The CSPI proposal would require any state supplying a retail establishment associated with a case to prove non-detectable levels of *V. vulnificus*. This puts an unreasonable burden on states that may not have a significant *V. vulnificus* problem.
2. Efforts are being made improve the safety of raw molluscan shellfish. The ISSC is considering new restrictions on the commercial harvest and sale of shellfish, which may present a significant hazard to particularly susceptible consumers.
3. There is insufficient information now to determine levels of *V. vulnificus*, which constitute a public health hazard.

We are devoted to providing quality shellfish that are safe for human consumption. We are working with the Washington State Department of Health, Tribal Managers, the regional FDA Office and the Pac Rim Shellfish Conference as well as the ISSC to address concerns associated with health hazards to the general public from *Vibrio sp.* in raw molluscan shellfish

We appreciate the opportunity to comment on this petition and state our concerns. Please contact Alan Chapman, Lummi Natural Resources at 360 384-2202, if you have any questions regarding these concerns.

Sincerely yours,


Merle Jefferson
Director, Natural Resources

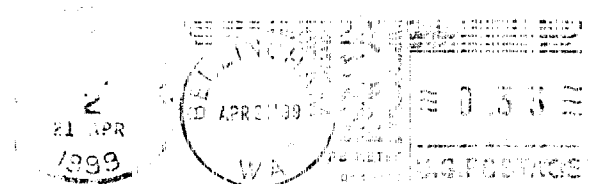
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